

## EXHIBIT 5

initial reading was not completely negative. However, the authors calculated their odds ratios of the differences between the initial and consultant B readers on the premise that only if all 6 consultants read the film as not completely negative was the radiograph considered not completely negative by the consultants. The odds ratios of the difference would be appreciably less if the 143 radiographs that were read as not completely negative by at least 3 of the 6 consultants were considered to be not completely negative.

Even with the re-calculation of the statistics in a more equitable manner, differences, though not as striking, will remain between the initial and the consultants' readings. The process of selecting B readers for this type of study, and how the data are analyzed so that outliers are eliminated, are of the utmost importance if we are to address the problem of how B readings are used in litigation and which individual truly has an abnormal radiograph.

As a B reader and epidemiologist for 20 years, who has mainly (> 90% of the time) read chest radiographs for research studies and governmental programs, I share the concern expressed in the editorial on whether something is rotten or not and the need to have independent studies performed to assess this issue.

#### Author's disclosure:

The author has received fees from both plaintiffs and defense attorneys as an expert witness and for performing independent medical examinations.

#### REFERENCES

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#### From:

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#### To the Editor:

In their article on the comparison of B readers' interpretation of chest radiographs for asbestos-related changes (1), Gitlin and co-authors present the results of a multi-reader comparison of radiographic readings for pneumoconiosis, and conclude that "there is not support in the literature on X-ray studies of workers exposed to asbestos and other mineral dusts for the high level of positive findings recorded by the initial readers in this report."

We take issue with many of the points in their article, but would like here to focus on the methods used in the study they discuss. The study, done at Johns Hopkins Medical Center, consisted of a re-reading of chest radiographs of plaintiffs in asbestos litigation, originally read by doctors (B readers) selected by plaintiffs' attorneys. The re-reading was done by a panel of B readers selected by the study's authors; the study was done at the behest of attorneys for defendants in asbestos litigation. We ask the following questions:

1. How were the "consultant" readers selected by the study's authors? There is no basis to judge the independence of the consultant B readers. The paper states that the consultant readers were "compensated for their participation." Was this by defense attor-

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neys? If so, does that not create the appearance, if not the reality, of conflict on the part of the consultants who re-read the radiographs?

2. How was the set of 551 cases chosen? Since these films were of individuals who had retained an attorney in asbestos litigation, we can presume that all of the films had been interpreted as showing some asbestos-related disease. This is confirmed by Table 2a in Gitlin and colleagues' article. There are thousands of such cases filed each year. If these 551 cases were ones consecutively received by a specific asbestos trust fund, they could be considered representative. The authors have an obligation to describe the method used for choosing the case sample for the study, rather than stating that they have no idea how the sample was chosen. In addition, the reason for the reduction of the initial sample of 551 to the final analytic sample of 492 is not clear.
3. Because this is a selected series of positive radiographs submitted for compensation, it is not appropriate to conclude that "there is not support in the literature on X-ray studies of workers exposed to asbestos and other mineral dusts for the high level of positive findings recorded by the initial readers in this report." The sample tells us nothing about a rate of positive findings among all exposed workers screened, or even the proportion read as positive by this select group of initial B readers. The study simply does not have any denominator data upon which to base such a conclusion.
4. Although the consultant readers disagreed with the initial readers, they disagreed among themselves as well. For many of the comparisons made in this paper, the agreement among the consultants was at best fair (Table). In making the kind of comparisons made in this study, some amount of agreement is expected by chance alone. The  $\kappa$  statistic adjusts for this chance agreement. Kappa is positive when agreement is better than chance (a value of 1 equals complete agreement), is zero when agreement equals what would be expected by chance, and is negative when agreement is worse than would be expected by chance. Landis and Koch (2) have suggested that  $\kappa$  values greater than about 0.75 represent excellent agreement, values between 0.40 and 0.75 indicate fair to good agreement, and values below about 0.40 represent poor agreement beyond chance.

**Table**  
**Kappa Statistic for Agreement among Consultant Readers**

Parameter	Kappa Statistic for Agreement among Consultant Readers	Kappa Descriptor
Film quality	0.10 (0.08–0.12)	Poor
Is film completely negative?	0.43 (.40–.46)	Fair
Any parenchymal abnormalities consistent with pneumoconiosis?	0.31 (0.28–0.33)	Poor
Small opacities 1/0 or greater?	0.19 (0.18–0.21)	Poor
Any pleural abnormalities consistent with pneumoconiosis?	0.49 (0.47–0.52)	Fair

In the study described by Gitlin and colleagues, there is a clear difference between the initial reader and the consultant readers in the overall classification of films as completely normal or not. However, additional statistical analyses showed poor to fair agreement among the "consultant" readers for chest-radiograph film quality, any parenchymal abnormality, and profusion category. Adding the initial reader to the measure of agreement did not change the value of the  $\kappa$  statistic for film quality, and only changed it slightly for the finding of whether or not the film was completely negative and for the finding of pleural abnormalities consistent with pneumoconiosis. In essence, the initial reader was in the same ballpark as the consultant readers for many of the important parameters evaluated. Prior literature documents that there is a great deal of variability in classification of radiographs using the International Labour Office (ILO)-1980 system. But one cannot really conclude from this analysis that the consultant readers were any more accurate than the initial readers. An analysis of each reader in comparison to the other five consultant readers would have been illustrative (3), to show the range of agreement among the consultant readers as well as with the initial reader.

5. The ILO classification system was not designed to be used as a diagnostic test, and the diagnosis of asbestosis requires more than a radiographic interpretation. The American Thoracic Society recently issued a new set of guidelines for the clinical diagnosis of non-malignant lung disease related to asbestos (4). We agree with Gitlin and colleagues that classification based on a single radiograph is subject to observer variability, and should not be used as the only criterion for a di-

agnosis of asbestos-related disease. It is important for the physician diagnosing asbestosis not to rely on chest radiographs alone, and in fact the Association of Occupational and Environmental Clinics has stated that such an act is unethical (5). There are additional and medically necessary steps to reach a diagnosis of asbestosis. However, we cannot support the conclusions of Gitlin and colleagues' study because of the potential bias in the selection of the study sample, the potential bias on the part of the consultant readers, and the clear high rate of variability among the consultant readers.

#### Authors' disclosure statement:

The authors of this letter have done medical-legal work in the area of asbestos-related disease in the form of medical reports and testimony for patients seen in their clinical practice, and in some cases for individuals not examined. The major portion of this work has been for plaintiffs' attorneys. For this work we have received consultation fees. Our research in the area of asbestos-related disease has not been funded by attorneys, nor have other relevant activities, such as testimony before the U.S. Congress or the drafting of published guidelines for the diagnosis and treatment of asbestosis.

#### REFERENCES

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#### From:

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#### To The Editor:

Gitlin and colleagues have revisited the problem of variability in the interpretation of radiographs obtained for the purpose of detecting asbestos-related abnormalities (1). The problem that they address has persisted for too long, and is worth re-examining so long as it persists.

The documented findings are expected. First, the authors used a methodology that is not designed to understate the problem, beginning with films interpreted by B readers retained by plaintiffs' attorneys. Second, very substantial differences in reader behavior were inferred between readers in our much larger study two decades ago. This earlier study was not conducted in the context of legal proceedings, and relied on very large numbers of randomly distributed packets of radiographs obtained on behalf of the U.S. Navy (and its substantial industrial operations, including shipyards). Despite the large numbers of films for each reader and the absence of a legal setting, it was clear that epidemics could appear and disappear depending on the choice of reader (2).

The impact of B-reader behavior was substantial then, and not unidirectional. For 23 high-volume B-readers, Navy data abnormalities  $\geq 1/0$  ranged from 0.05% to 10.93% (median: 1.71%), and from 0.02% to 7.55% for  $\geq 1/1$ , encompassing several orders of magnitude (4). While "over-reading" is emphasized in the article by Gitlin and colleagues and the accompanying editorial by Janower and Berlin (3), the failure to find existing disease is generally regarded as the most serious problem in medical surveillance efforts. Because the normative film in most samples will be normal, an "over-reader" may appear more culpable than an "under-reader" in the types of statistical analyses that both we and Gitlin and colleagues applied. Both over-reading and under-reading are important problems; deciding which is the more culpable error is a matter of perspective. Quality assurance is a good for the goose as well as for the gander.

It has been clear for two decades that the social utility of the B-reading program as currently configured is problematic. The assertion that the International Labour Office system was "designed for research" is merely a failure to address the social problem. That failure in turn affects the health beliefs of our patients. The B-reading process is also referred to in U.S. Occupational Safety and Health Administration law (1910.1001). It is time to stop pretending that the testing examination alone provides sufficient quality assurance to address the needs of exposed populations. The solution attributed to me by Gitlin and colleagues (1), of multiple readings, is likely to be an